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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,118

06/20/2003

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,118	Applicant(s) CIMINO, WILLIAM W.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-3, 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock et al (US 5549672) in view of Wheeldon et al (US 4670007). Maddock discloses a device and method for filling mammary prostheses and tissue expanders. The system rapidly delivers and accurately monitors the delivery of a desired volume of sterile fluid to an implantable device (col. 2, lines 49-58) and comprises a container of sterile fluid 20, a pump 58, a sterile tubing set 24, a display 68 for displaying the amount of fluid delivered (col. 6, lines 7-9). Maddock discloses that the tubing set may be made of PVC (col. 7, lines 3-4).
3. Maddock discloses that the device delivers fluid from the container through sterile tubing and to the implant. Therefore the steps of connecting the sterile tubing set and making the end of the tube available for delivery of the fluid by the pump to the surgery site are inherently disclosed.
4. Maddock does not disclose the speed of the pump. However, it is well known in the art that peristaltic pumps such as the one disclosed by Maddock are capable of delivering fluid at virtually any rate. Maddock also does not explicitly disclose the volume of fluid delivered. Maddock discloses that the device is capable of rapidly filling a breast implant, and applicant discloses that for filling breast implants, volumes of interest are typically from 100-500ml (p.5, lines 18-19 of specification). Therefore, it would have been obvious that the volume delivered would be the volume known to be typical for breast implants.

5. Maddock discloses that the device may include volume measuring capabilities (col. 2, lines 49-50) as determined by the pump speed. Claim 1 calls for the volume measuring capabilities to be a strain gauge and processor. Claim 10 similarly calls for the container to be supported from a strain gauge sensor, and a processor to process the signal from the sensor to display the volume of fluid. Wheeldon teaches a device for controlling the amount of fluid delivered to a patient including a sterile fluid source attached to a strain gauge which monitors the delivery rate and displays either the delivery rate or the total dose amount on a display. Wheeldon teaches that monitoring the flow rate and volume delivered using a strain gauge is preferable to other methods known in the art such as monitoring the speed of a peristaltic pump as is disclosed by Maddock because it does not require calibration of the device and eliminates variations in tubing performance (col. 1, line 59 - col. 2, lines 40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock to include the volume monitoring system of Wheeldon (including a strain gauge and processor) because Wheeldon teaches that using a strain gauge is preferable to simply monitoring the RPM of the pump because it allows for better control and accuracy and eliminates variables such as tubing performance. The sterile fluid bag of Maddock is disclosed as hanging from an IV pole so the strain gauge system could easily be included without changing the functioning of the device of Maddock.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock in view of Wheeldon as applied to claim 1 above, and further in view of Savage et al (US 6319221). Maddock and Wheeldon are silent as to a reset button. Savage teaches a weighing system that includes a reset button that will zero the display to allow the user to reset the system and monitor

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the changes in weight in a new time period (col. 8, lines 1-15). This feature is beneficial in a system such as the one disclosed by Maddock were the pump will be used to fill two breast implants. The volume of fluid delivered to the first implant can be measured, the display reset and the volume delivered to the second implant can be measured.

Response to Arguments

7. Applicant's arguments, see page 8, filed 9/3/09, with respect to the rejection(s) of claim(s) 1, 10 under DeSatnick have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Maddock.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763